

Patency and Life-Spans of Failing Hemodialysis Grafts

in Patients Undergoing
Repeated Percutaneous De-Clotting

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We set out to determine retrospectively the primary and secondary patency rates, as well as the life-spans, of failing polytetrafluoroethylene dialysis grafts after repeated percutaneous mechanical de-clotting.

The study group consisted of all patients who had undergone percutaneous mechanical de-clotting, balloon angioplasty, or angiography of their polytetrafluoroethylene hemodialysis grafts at our institution from 1 January through 30 April 1999. Patency of the hemodialysis grafts was calculated using Kaplan-Meier analysis.

A total of 161 percutaneous de-clotting procedures were performed on 59 of 71 patients. At 1 year, the primary and secondary surgical patency rates of the grafts were 29% and 61.4%, respectively. The life-spans of the polytetrafluoroethylene grafts after repeated percutaneous de-clotting and surgical interventions was 93.5% at 6 months, 78% at 1 year, 58.8% at 2 years, and 35% at 3 years. The patency rates after the 1st, 2nd, and 3rd de-clotting procedures were 55.9%, 61.9%, and 55.8% at 3 months and 32.2%, 40.8%, and 31.4% at 6 months, respectively ($P=0.40$). The patency rate of grafts after mechanical de-clotting using the Arrow-Trerotola thrombectomy device was not statistically different from that of the crossed angioplasty balloon technique alone ($P=0.38$). Further, there was no difference in the life-spans of grafts whether they were located in the upper or lower extremity.

Because reocclusion rates are similar following 1st, 2nd, and 3rd occlusions, regardless of the percutaneous mechanical de-clotting technique used, repeated percutaneous management should be undertaken to preserve each graft regardless of the number of previous de-clotting procedures. (Tex Heart Inst J 2001;28:249-53)

Key words: Angioplasty, balloon; catheterization, peripheral; comparative study; graft occlusion, vascular/therapy; kidney failure, chronic/complications; outcome assessment (health care); polytetrafluoroethylene; radiography, interventional; recurrence; renal dialysis/adverse effects; retrospective studies; thrombectomy/methods; vascular patency

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Despite a steady increase in the number of patients with end-stage renal disease (ESRD), the number of hospital admissions related to vascular access for hemodialysis has decreased 17% from 1994 to 1998.¹ This is in part secondary to the development and improvement of outpatient procedures for the management of hemodialysis access. An increasing number of patients with ESRD who require hemodialysis are being managed with surgically placed polytetrafluoroethylene arteriovenous (PTFE A-V) grafts. However, failure of these grafts as a consequence of thrombosis is a common problem that requires prompt intervention. Previously, surgical treatment was the only option for management of graft failure, but percutaneous methods are now in wide use. Current techniques for percutaneous de-clotting of hemodialysis PTFE grafts are pharmacologic thrombolysis and mechanical thrombectomy by means of angioplasty balloons or hydrodynamic devices. The most widely studied de-clotting technique, originally described by Trerotola and colleagues,² uses crossed angioplasty balloons to clear thrombus from the PTFE graft. Primary patency rates with this technique have ranged from 37% to 52% at 3 months, 31% to 36% at 6 months, and 8% to 17% at 12 months.²⁻⁵

We studied a series of patients with failing PTFE grafts who were treated with the crossed angioplasty balloon technique alone or in combination with the Arrow-Trerotola percutaneous thrombolytic device, in order to determine the percutaneous patency rate as well as the primary and secondary surgical patency rates and the life-spans of the grafts.

Methods

Using our radiology computer databank, we identified all patients who had undergone fistulography of dialysis grafts with or without percutaneous intervention

(including angioplasty or mechanical de-clotting) from 1 January through 30 April 1999. All patients were studied with the intention to treat, except for those with grafts less than 4 weeks of age and those with suspected infection. Of a total of 111 patients identified, surgical data including date of the shunt creation were available in 85 patients. Of these 85 patients, 14 were excluded from the study: 9 developed infection of the PTFE graft and 5 received renal transplants. Therefore, the study group consisted of 71 patients (37 males and 34 females), ranging in age from 13 to 84 years (mean, 54 ± 16 years).

The following types of PTFE grafts were inserted: 40 forearm loop grafts, 23 straight upper-arm grafts, and 8 thigh loop grafts. The results of all diagnostic and therapeutic radiologic procedures and surgical procedures performed on these grafts, both during the period under review and before and after that period, were recorded and then analyzed in retrospect. The percutaneous patency rates, the primary and secondary surgical patency rates, and the life-spans of the grafts were all calculated using Kaplan-Meier analysis (SAS system). Primary surgical patency was defined as the period of time between surgical placement of the PTFE graft and the 1st occlusion. Percutaneous patency refers to the time during which the graft remained patent after percutaneous de-clotting for each occlusion event. Secondary surgical patency refers to the time between surgical placement of the graft and surgical thrombectomy or revision. One or more percutaneous de-clotting procedures were performed during this period of time. The end-point for secondary surgical patency was surgical thrombectomy or revision. The graft life-span was defined as the length of time from graft placement to any occlusion that could not be managed by means of percutaneous or surgical procedures, including thrombectomy and revision of the venous anastomosis. This end-point required placement of a hemodialysis catheter with or without surgical placement of a new PTFE graft or fistula.

Mechanical graft de-clotting was performed by means of the crossed angioplasty balloon technique (CABT) as described by Trerotola's group, either alone or in combination with the Arrow-Trerotola percutaneous thrombolytic device (ATTD) (Arrow International, Inc.; Reading, Penn), in a manner similar to that described in the clinical trials of the device.^{2,6} Each patient received 2,500 U of heparin intravenously after successful crossing of the venous anastomosis. The venous anastomosis was dilated using 7- or 8-mm-diameter angioplasty balloons (Boston Scientific; Natick, Mass) in forearm and upper-arm grafts, and 8- or 9-mm angioplasty balloons in thigh grafts, depending on the diameter of the venous outflow. The arterial anastomosis was di-

lated with use of a 6-mm angioplasty balloon. Duration of patency after the 1st, 2nd, 3rd, and 4th mechanical de-clotting procedures was analyzed in accordance with graft location, the age of the patient, the de-clotting technique (CABT or ATTD), and the size of the angioplasty balloon. The probability of statistical difference between groups was calculated by the log-rank test.

Results

A total of 161 percutaneous de-clotting procedures were performed on 59 of 71 patients. De-clotting procedures per patient ranged from 0 to 9, with an arithmetic mean of 2.3 per patient. The 12 patients who did not require percutaneous de-clotting of their grafts underwent surveillance fistulography and received balloon angioplasty as indicated.

The crossed angioplasty balloon technique was used alone in 61 procedures, and was used in combination with the Arrow-Trerotola percutaneous thrombolytic device in another 91 procedures. In 9 additional procedures, a 3rd de-clotting technique was used in combination with the crossed angioplasty balloon technique to achieve lysis: the AngioJet Rheolytic Thrombectomy System (Possis Medical Inc.; Minneapolis, Minn) ($n=6$), urokinase ($n=2$), or the Hydrolyser thrombectomy catheter (Cordis Endovascular; Miami, Fla) ($n=1$). These procedures were technically successful in 155 out of 161 occlusion events. A technically successful procedure was defined as restoration of flow that enabled at least 1 dialysis treatment. Of the 6 technical failures, 1 was due to inability to cross the venous anastomosis with a guide wire, a 2nd was due to excessive thrombus in the subclavian vein, and a 3rd was due to multiple large pseudoaneurysms in the graft. The other 3 failures were not associated with any identifiable cause other than the inability to maintain patency of the lumen despite multiple attempts to clear the graft. The only major complication, venous perforation after angioplasty, was successfully managed without surgery by placement of a Wallstent (Boston Scientific Corp.; Natick, Mass) across the site of leakage, which stopped the extravascular flow.

Of the 59 patients who required percutaneous de-clotting procedures, 11 underwent 1 procedure, 19 underwent 2 procedures, 11 underwent 3 procedures, 12 underwent 4 procedures, 3 underwent 5 procedures, 2 underwent 6 procedures, and 1 underwent 9 procedures. Graft patency after the 1st, 2nd, 3rd, and 4th percutaneous de-clotting of the PTFE graft is illustrated in Table I.

Graft patency after the 1st percutaneous de-clotting procedure using ATTD ($n=36$) was not significantly different ($P=0.44$) from graft patency using the

TABLE I. Patency of Polytetrafluoroethylene Hemodialysis Grafts after Percutaneous De-Clotting Using the Arrow-Trerotola Thrombolytic Device or the Crossed Angioplasty Balloon Technique

Procedure	Patients (n)	Patency at 3 Mo (%)	Standard Error (%)	Patency at 6 Mo (%)	Standard Error (%)	Patency at 12 Mo (%)	Standard Error (%)
1st mechanical de-clotting	59	55.9	6.5	32.2	6.1	9.0	3.9
Arrow-Trerotola thrombolytic device	36	55.6	8.3	30.6	7.8	13.9	5.8
Angioplasty balloon de-clotting	18	50.0	11.8	27.8	10.6	0	0
Other*	5	—	—	—	—	—	—
2nd mechanical de-clotting	38	61.9	6.9	40.8	7.1	17.8	8.2
Arrow-Trerotola thrombolytic device	22	67.7	8.4	36.0	8.9	13.5	6.7
Angioplasty balloon de-clotting	15	50.0	12.5	50.0	12.5	22.5	11.0
Other*	1	—	—	—	—	—	—
3rd mechanical de-clotting	28	55.8	9.2	31.4	8.6	23.5	8.1
Arrow-Trerotola thrombolytic device	19	50.8	11.8	22.6	9.9	16.9	8.9
Angioplasty balloon de-clotting	8	62.5	17.1	37.5	17.1	18.8	15.8
Other*	1	—	—	—	—	—	—
4th mechanical de-clotting	19	68.4	10.7	45.6	11.7	22.8	10.0
Arrow-Trerotola thrombolytic device	10	80.0	12.7	40.0	15.5	20.0	12.7
Angioplasty balloon de-clotting	7	71.4	17.1	71.4	17.1	35.7	19.8
Other*	2	—	—	—	—	—	—

*Other percutaneous de-clotting techniques involved the use of the AngioJet Rheolytic Thrombectomy System, the Hydrolyser thrombectomy catheter, or urokinase as an adjunct to the crossed angioplasty balloon de-clotting technique.

CABT (n=18). Similarly, no significant differences in graft patency were found after the 2nd ($P=0.75$), 3rd ($P=0.66$), and 4th ($P=0.38$) de-clotting procedures.

The primary surgical patency of the grafts in this group of patients as determined by Kaplan-Meier survival curves was $47.4\% \pm 6.0\%$ (SD) at 6 months, $29\% \pm 5.4\%$ at 1 year, and $16\% \pm 4.8\%$ at 2 years (Fig. 1). The secondary surgical patency was $74.7\% \pm 5.3\%$ at 6 months, $61.4\% \pm 6.0\%$ at 1 year, and $37.8\% \pm 6.8\%$ at 2 years (Fig. 2). A total of 39 patients required surgical revision of the venous anastomosis. Three of the 39 had undergone prior surgical thrombectomy. Seven additional patients had surgical thrombectomy alone. The life-spans of the PTFE grafts after repeated percutaneous de-clotting and surgical interventions were $93.5\% \pm 2.9\%$ at 6 months, $78\% \pm 5.0\%$ at 1 year, $58.8\% \pm 6.5\%$ at 2 years, and $35\% \pm 8.0\%$ at 3 years (Fig. 3). The life-spans of PTFE grafts were also analyzed (Fig. 3) by location (forearm, upper arm, and thigh), and no statistically significant differences in values were found ($P=0.51$). Also, statistical analysis of graft life-spans in the following age groups—younger than 40, 40 through 60, and older than 60 years of age—disclosed no significant difference ($P=0.51$).

Discussion

Driven principally by advances in medical technology and accessibility of health care, the ESRD patient population continues to grow. This growth has placed greater importance on the development of effective techniques for the creation and preservation of hemodialysis access. The most widely used types of permanent hemodialysis access in the United States are the PTFE graft and the autogenous A-V fistula. The percentage of ESRD patients who begin hemodialysis with PTFE grafts increased steadily from 51% in 1986 to 65% in 1990,⁷ and is probably higher than that now. In early surgical studies, the mean life-span of an upper-extremity PTFE graft was found to be 1.9 to 2.1 years, compared with 1.6 years in the lower extremity.^{8,9} Surgical experience appears to play a role in the variation of patency rates of PTFE grafts.⁷

A number of research groups¹⁰⁻¹⁴ have shown that surveillance programs prolong survival of PTFE hemodialysis grafts if they conduct hemodynamic monitoring, fistulography, and maintenance angioplasty. However, thrombosis remains a frequent problem for the ESRD population, despite enrollment in these programs.

Percutaneous techniques for de-clotting PTFE grafts have proved effective and safe in short-term follow-up studies (3, 6, and 12 months)²⁻⁴ in which the

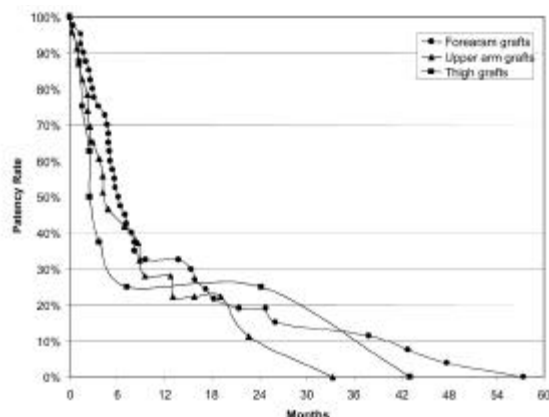


Fig. 1 Primary surgical patency of hemodialysis grafts by location.

Standard error <0.05 at all points.

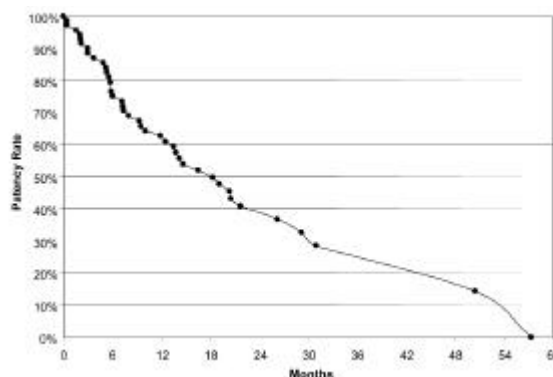


Fig. 2 Secondary surgical patency of hemodialysis grafts.

Standard error <0.10 at all points.

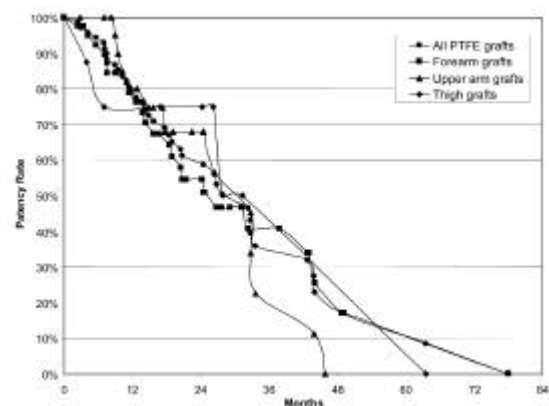


Fig. 3 Life-spans of hemodialysis grafts following percutaneous and surgical interventions.

Standard error <0.11 for forearm grafts, <0.15 for upper-arm grafts, and <0.23 for thigh grafts at all points. PTFE = polytetrafluoroethylene

crossed angioplasty balloon technique was used without pharmacologic lysis. Reports on the effectiveness of the Arrow-Trerotola percutaneous thrombolytic device for de-clotting PTFE grafts have shown similar short-term primary patency rates.^{6,15} The patients in our study exhibited similar patency rates, regardless of the method of percutaneous mechanical declotting.

The 1-year primary surgical patency rate ($29\% \pm 5.4\%$) for PTFE grafts in our study is lower than the 41% to 52% reported in the surgical literature.¹⁶⁻¹⁸ However, our primary patency rate is slightly higher than the 1-year primary patency of 23% reported by Safa and co-authors¹⁹ in a similar group of patients with graft dysfunction.

The secondary surgical patency rates for PTFE grafts that are reported in the literature range from 59% to 96% at 1 year and 50% to 78% at 2 years.¹⁶⁻¹⁸ Our secondary patency rate of $61.4\% \pm 6.0\%$ at 1 year is similar. Seen in the light of our comparatively low primary surgical patency rate at 1 year, our secondary rate indicates that even those grafts that fail relatively early after surgical placement can remain patent in the longer term when managed with repeated percutaneous treatment.

Published percutaneous patency rates of PTFE dialysis grafts after percutaneous mechanical de-clotting range from 37% to 52% at 3 months, 31% to 36% at 6 months, and 8% to 17% at 12 months.²⁻⁵ In our study, graft patency after the 1st de-clotting procedure ($n=56$) is very similar to that of the published rates ($55.9\% \pm 6.5\%$ at 3 months, $33.2\% \pm 6.1\%$ at 6 months, and $9\% \pm 3.9\%$ at 1 year).

As illustrated in Fig. 4, the percutaneous patency of PTFE grafts after the 1st, 2nd, and 3rd mechanical de-clotting procedures was similar ($P=0.40$), a finding

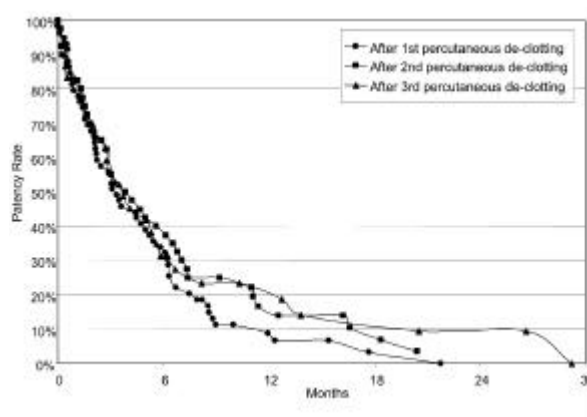


Fig. 4 Hemodialysis graft patency following the 1st, 2nd, and 3rd percutaneous de-clotting procedures is very similar. Patency was determined for each consecutive de-clotting procedure and was defined as the period of time the graft remained patent, to the next occlusion event.

Standard error <0.06, <0.07, and <0.09 for the 1st, 2nd, and 3rd de-clotting procedures, respectively.

also described by Beathard.⁵ Given the limited number of sites suitable for placement of dialysis A-V grafts or fistulae, one should make every attempt to restore flow in the existing graft. The only patients whose grafts we do not try to de-clot are those who have suspected graft infection, those who have undergone initial surgical placement or surgical revision within 4 weeks of thrombosis, and those who have undergone percutaneous declotting within 3 weeks.

Our study also confirms the safety and effectiveness of continual percutaneous management. Only 1 complication—a venous anastomotic laceration—occurred, and this was treated successfully by percutaneous means, with a self-expanding, non-covered stent.

In conclusion, we found no difference in patency rates between the 2 mechanical thrombectomy techniques. Moreover, the percutaneous patency rates of PTFE hemodialysis grafts after the 1st, 2nd, and 3rd mechanical percutaneous de-clotting procedures are similar. Until better techniques become available for creation of permanent hemodialysis access, maximal efforts should be undertaken to preserve each graft regardless of the number of previous de-clotting procedures.

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References

1. Economic cost of ESRD. In: U.S. Renal Data System, USRDS 2000 Annual Data Report: Atlas of End-Stage Renal Disease in the United States. Washington, DC: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda (MD); 2000. p. 163-75.
2. Trerotola SO, Lund GB, Scheel PJ Jr, Savader SJ, Venbrux AC, Osterman FA Jr. Thrombosed dialysis access grafts: percutaneous mechanical declotting without urokinase. *Radiology* 1994;191:721-6.
3. Middlebrook MR, Amygdalos MA, Soulen MC, Haskal ZJ, Shlansky-Goldberg RD, Cope C, Pentecost MJ. Thrombosed hemodialysis grafts: percutaneous mechanical balloon declotting versus thrombolysis. *Radiology* 1995;196:73-7.
4. Soulen MC, Zaetta JM, Amygdalos MA, Baum RA, Haskal ZJ, Shlansky-Goldberg RD. Mechanical declotting of thrombosed dialysis grafts: experience in 86 cases. *J Vasc Interv Radiol* 1997;8:563-7.
5. Beathard GA, Welch BR, Maidment HJ. Mechanical thrombolysis for the treatment of thrombosed hemodialysis access grafts. *Radiology* 1996;200:711-6.
6. Trerotola SO, Vesely TM, Lund GB, Soulen MC, Ehrman KO, Cardella JF. Treatment of thrombosed hemodialysis access grafts: Arrow-Trerotola percutaneous thrombolytic device versus pulse-spray thrombolysis. Arrow-Trerotola Percutaneous Thrombolytic Device Clinical Trial. *Radiology* 1998;206:403-14.
7. Hakim R, Himmelfarb J. Hemodialysis access failure: a call to action. *Kidney Int* 1998;54:1029-40.
8. Zibari GB, Rohr MS, Landreneau MD, Bridges RM, DeVault GA, Petty FH, et al. Complications from permanent hemodialysis vascular access. *Surgery* 1988;104:681-6.
9. Taylor SM, Eaves GL, Weatherford DA, McAlhany JC Jr, Russell HE, Langan EM 3rd. Results and complications of arteriovenous access dialysis grafts in the lower extremity: a five year review. *Am Surg* 1996;62:188-91.
10. Roberts AB, Kahn MB, Bradford S, Lee J, Ahmed Z, Fitzsimmons J, Ball D. Graft surveillance and angioplasty prolongs dialysis graft patency. *J Am Coll Surg* 1996;183:486-92.
11. Kanterman RY, Vesley TM, Pilgram TK, Guy BW, Windus DW, Picus D. Dialysis access grafts: anatomic location of venous stenosis and results of angioplasty [published erratum appears in *Radiology* 1995;196:582]. *Radiology* 1995;195:135-9.
12. Turmel-Rodrigues L, Pengloan J, Blanchier D, Abaza M, Birmele B, Haillot O, Blanchard D. Insufficient dialysis shunts: improved long-term patency rates with close hemodynamic monitoring, repeated percutaneous balloon angioplasty, and stent placement. *Radiology* 1993;187:273-8.
13. Sands JJ, Jabyac PA, Miranda CL, Kapsick BJ. Intervention based on monthly monitoring decreases hemodialysis access thrombosis. *ASAIO J* 1999;45:147-50.
14. Martin LG, MacDonald MJ, Kikeri D, Cotsonis GA, Harker LA, Lumsden AB. Prophylactic angioplasty reduces thrombosis in virgin ePTFE arteriovenous dialysis grafts with greater than 50% stenosis: subset analysis of a prospectively randomized study. *J Vasc Interv Radiol* 1999;10:389-96.
15. Lazzaro CR, Trerotola SO, Shah H, Namyslawski J, Moresco K, Patel N. Modified use of the Arrow-Trerotola percutaneous thrombolytic device for the treatment of thrombosed hemodialysis access grafts. *J Vasc Interv Radiol* 1999;10:1025-31.
16. Cinat ME, Hopkins J, Wilson SE. A prospective evaluation of PTFE graft patency and surveillance techniques in hemodialysis access. *Ann Vasc Surg* 1999;13:191-8.
17. Hurlbert SN, Mattos MA, Henretta JP, Ramsey DE, Barkmeier LD, Hodgson KJ, Summer DS. Long-term patency rates, complications and cost-effectiveness of polytetrafluoroethylene (PTFE) grafts for hemodialysis access: a prospective study that compares Impira versus Gore-tex grafts. *Cardiovasc Surg* 1998;6:652-6.
18. Hodges TC, Fillinger MF, Zwolak RM, Walsh DB, Bech F, Cronenwett JL. Longitudinal comparison of dialysis access methods: risk factors for failure. *J Vasc Surg* 1997;26:1009-19.
19. Safa AA, Valji K, Roberts AC, Ziegler TW, Hye RJ, Oglevie SB. Detection and treatment of dysfunctional hemodialysis access grafts: effect of a surveillance program on graft patency and incidence of thrombosis. *Radiology* 1996;199: 653-7.